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Long-Term Angiographic and Clinical Outcome After Implantation of a Balloon-Expandable Stent in the Native Coronary Circulation

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Objectives. **The purpose of this study was to examine the long-term clinical and angiographic outcome after coronary stent implantation.**

Background. **Previous reports have shown a discordance between the excellent initial angiographic results and subsequent adverse clinical events after coronary artery stenting.**

Methods. **Single Palmaz-Schatz stents were electively implanted in the native coronary arteries of 300 consecutive patients. Angiograms were obtained at baseline, after balloon angioplasty, after stent implantation and at 6 months after implantation. Films were analyzed by a panel of angiographers utilizing an automated edge detection program. Clinical events, including death, myocardial infarction, coronary bypass surgery and repeat angioplasty, were recorded for 1 year.**

Results. **Although there were no acute in-laboratory vessel closures, stent thrombosis occurred in 14 patients (4.7%) at a mean ±SD of 5 ± 3 days after implantation. Two hundred fifty-eight (90%) of 286 eligible patients had follow-up angiography at 6.1 ± 2.2 months after stent implantation. Minimal lumen diameter increased from 0.80 ± 0.39 mm at baseline to 1.65 ± 0.51 mm after angioplasty and further increased to 2.55 ± 0.49 mm after stent placement ($p = 0.0001$). At follow-up there was a 0.85-mm late loss in lumen diameter, with a final minimal lumen diameter at 6 months of 1.70 ± 0.71 mm. Restenosis, defined as ≥50% diameter stenosis at follow-up, occurred in 14% of patients with previously untreated lesions and in 39% of patients with previous angioplasty ($p < 0.001$). Clinical events after 1 year for the entire group of 300 patients included death in 0.7%, myocardial infarction in 3.7%, bypass grafting in 8% and repeat angioplasty in 13%. Freedom from any adverse clinical event was 80% for all treated patients and 87% for those with previously untreated lesions.**

Conclusions. **Elective use of this balloon-expandable stent in the native coronary circulation is associated with a low restenosis rate by quantitative angiography in previously untreated lesions and a favorable clinical outcome with an excellent event-free survival rate at 1 year.**

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Coronary stents have been proposed as a means of overcoming two major limitations of balloon angioplasty—sudden early vessel closure and late restenosis. The initial enthusiasm for this technology has been dampened by reports of high rates of thrombosis for self-expanding stents (1). The device used in this trial was a balloon-expandable, stainless steel stent (Palmaz-Schatz stent) whose initial efficacy has been described (2). Previous studies (2–4) have included patients who differed in clinical indications for device placement, baseline characteristics and the use of multiple or single stents. The specific goal of this study was to assess angiographic restenosis and long-term clinical outcome in a consecutive series of patients undergoing elective revascularization with a single Palmaz-Schatz stent.

Methods

Device description. The 15-mm long Palmaz-Schatz stent is composed of two 7-mm rigid, slotted stainless steel tubes connected by a 1-mm central bridging strut (Johnson and Johnson Interventional Systems). In the first 30 patients, a

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prototype device without a central strut was used. When expanded by a standard 20-mm length angioplasty balloon, the rectangular slots take on a diamond-shaped configuration with a large free space/metal ratio. In its deployed state, the device has a high level of radial noncompliance, thereby resisting compressive forces and elastic recoil. The individual metal struts are 0.12 mm wide and 0.06 mm thick. Previous canine experiments (5) have shown that the stent is covered by a platelet fibrin mesh within hours of implantation and is fully endothelialized within 4 weeks.

Before stent placement, all lesions were pretreated by dilation using conventional angioplasty balloons. The stent was deployed by inflating the delivery balloon to 5 to 6 bar. Procedural details of stent placement have been described previously (2). The adjunctive pharmacologic regimen was as follows: Before implantation, patients received aspirin (325 mg), dipyridamole (75 mg three times a day), a calcium antagonist and low molecular weight dextran 40 (begun 2 h preoperatively at 100 ml/h). During the procedure, patients received a ≥10,000-U bolus of heparin with a continuous infusion at ≥1,000 U/h (the activated clotting time was maintained at >300 s). Treatment with warfarin was started on the day of the procedure. After the procedure, heparin infusion was temporarily discontinued and femoral sheaths were removed when the activated clotting time was <180 s; heparin treatment was restarted 6 h later and continued until a therapeutic prothrombin time was achieved with warfarin. Warfarin was given for 1 month and dipyridamole for 3 months; aspirin therapy was continued indefinitely.

Study patients. The study group consisted of 300 consecutive patients who underwent elective placement of a single Palmaz-Schatz stent in a native coronary artery between December 1987 and June 1990. The protocol was approved by the Institutional Review Boards of the 12 participating sites and informed consent was obtained from all patients. During this study period, an additional 73 patients underwent coronary stenting on an unplanned, emergency "bailout" basis outside of the present protocol or with use of multiple stents, or both.

The clinical characteristics of the patients are shown in Table 1. Inclusion and exclusion criteria for enrollment into this trial as well as the immediate results after stenting have been previously described in detail (2). Eligibility criteria for stenting included objective evidence of myocardial ischemia, preserved left ventricular ejection fraction ≥50%, a coronary stenosis ≥70% (by visual estimate of the investigator) that could be completely spanned by a single 15-mm long stent, and a target vessel diameter ≥3 mm. Follow-up catheterization was performed at 6 months after stent implantation unless early restudy was indicated by symptoms. To assess the possibility that the metal implant might prolong the time course of restenosis, a second follow-up angiogram was performed on a prospective basis at 1 year in a cohort of 50 patients. Clinical follow-up status was obtained at 1 and 2 weeks and at 1, 2, 3, 6 and 12 months. The major clinical events assessed for this study were death, myocardial infarction and need for repeat revascularization.

Table 1. Clinical Characteristics of 300 Study Patients

Age (yr)	58 ± 11 (range 31 to 86)
Male/female	238/62
Angina class (CCS)	
0	24 (8%)
I	14 (5%)
II	61 (20%)
III	88 (29%)
IV	112 (38%)
Hypertension	124 (41%)
Diabetes	49 (16%)
Cholesterol >200 mg/dl	157 (54%)
Smoking (current)	39 (13%)

Values presented are number (%) of patients or mean value ± SD. CCS = Canadian Cardiovascular Society classification.

Angiographic analysis. Initial and follow-up angiograms were forwarded to the core angiographic laboratory at the Thomas Jefferson University Hospital, where films were analyzed by a panel of experienced angiographers as described elsewhere (6). Coronary angiography was performed after administration of intracoronary nitroglycerin (150 to 200 μg) at baseline, after balloon angioplasty, after stent implantation and at the 6-month follow-up study.

Quantitative analysis of the coronary segments of interest were performed by using a validated computer-based edge detection algorithm (7,8). Cine frames, in orthogonal views whenever possible, were selected by the panel before coronary angioplasty, after balloon dilation, after stent implantation and at follow-up. These cine frames were projected on a General Electric Caps 35-mm cine viewer optically coupled to a video camera. The video signal was digitized at 512 × 512 × 8-bit resolution onto a digital angiographic computer (model DPS-4100, ADAC Laboratories). Images were magnified fourfold and the region of interest was selected by the operator and the vessel lumen was automatically determined (Artrek program, ADAC Laboratories). Absolute measurements were made using the dye-filled guiding catheter as a scaling reference. The proximal and distal segments considered to be normal and outside the stented area were selected by the operator and averaged to determine the reference vessel dimension. Minimal lumen diameter, reference vessel diameter and percent diameter stenosis were then calculated as a mean value from the two orthogonal projections. The mean variability for repeated measurements performed by the core laboratory on different days is ±0.16 mm for minimal lumen diameter and ±4.2% for percent diameter stenosis.

End points. Restenosis was defined as ≥50% diameter stenosis on the follow-up angiogram. The following events were considered clinical end points: death, myocardial infarction, bypass surgery and repeat angioplasty during the 1st year. All myocardial infarctions were documented according to the criteria of the National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry described by Detre et al. (9), with at least two of the following:

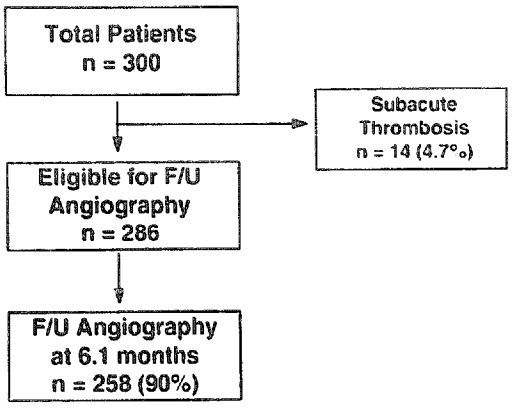


Figure 1. Flow diagram of 300 consecutive patients in whom a single stent was implanted in native coronary arteries. There was a 4.7% early thrombotic rate; follow-up (F/U) angiography was performed 6.1 ± 2.2 months after implantation in 90% of eligible patients.

clinical symptoms, presence of new Q waves ≥0.04 s and elevation in creatine kinase or MB fraction more than two times the upper limit of normal.

Statistical analysis. All data are expressed as mean value ± SD. Comparisons among baseline, postangioplasty and post-stent measurements were performed by two-way analysis of variance. Two-tailed *t* tests were applied for analysis of paired numeric data. The chi-square test was used to assess the relation of categoric variables to angiographic restenosis. A statistical probability of < 0.05 was considered significant.

Results

There were no acute in-laboratory vessel closures. Fourteen (4.7%) of 300 patients developed stent thrombosis at 5 ± 3 days after stent implantation (range 0 to 12 days). Of the 286 remaining eligible patients, 258 (90%) had late angiographic follow-up at 6.1 ± 2.2 months after stent implantation (Fig. 1). Clinical follow-up was obtained on all 300 patients at 12 months.

Angiographic outcome. Eighty-three patients (28%) had not previously undergone angioplasty of the study lesion. Eighty-six patients (29%) had one previous angioplasty procedure, and 131 patients (43%) had two or more previous angioplasty procedures. Thus, 72% of the stents were placed for restenotic lesions. Qualitative lesion characteristics before intervention are summarized in Table 2. Unfavorable morphologic features included eccentricity in 57%, complex ulceration in 36%, and intimal dissection resulting from angioplasty in 29%.

Baseline minimal lumen diameter was 0.80 ± 0.39 mm; this value increased to 1.65 ± 0.51 mm after initial angioplasty ($p = 0.0001$) and increased significantly further to 2.55 ± 0.49 mm after stent implantation ($p = 0.0001$). At 6-month follow-up, there was a net late loss of 0.85 mm to a final minimal lumen diameter of 1.70 ± 0.71 mm ($p = 0.001$ vs. immediate post-stent value). In Figure 2, these results are depicted using cumulative frequency of lesions plotted as a function of the minimal lumen diameter.

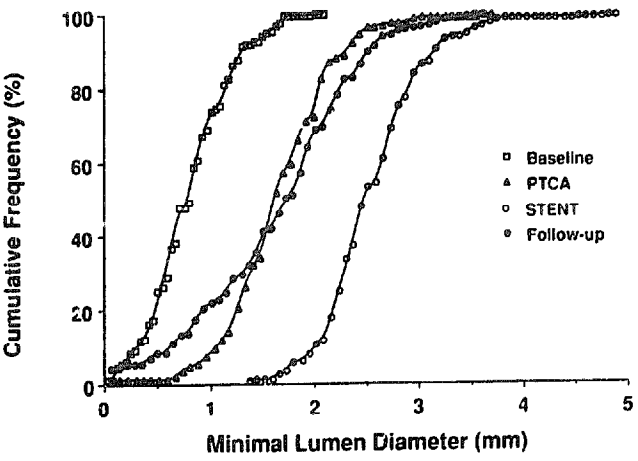
Table 2. Baseline Lesion Characteristics

Vessel diameter (mm) (mean ± SD)	3.08 ± 0.50
Lesion length (mm) (mean ± SD)	7.5 ± 4.1
Site of stent implantation (%)	
Left main coronary artery	0.3
Left anterior descending coronary artery	43
Left circumflex coronary artery	12
Right coronary artery	44
Morphologic feature of lesion (%)	
Eccentric	57
Ulcerated	36
Calcification	21
Bend ≥45°	12
Thrombus	5
Dissection after balloon angioplasty	29

Restenosis occurred in 14% of the previously untreated lesions and in 39% of lesions that had been previously dilated ($p < 0.001$). The restenosis rates were 40%, 43% and 30%, respectively, for lesions with one, two and three or more previous angioplasty procedures (Fig. 3). For lesions that had previously been dilated, there was no significant increase in restenosis risk as a function of the number of previous procedures.

Restenosis was not significantly affected by the location of the vessel stented. Restenosis rates of stents placed in the left anterior descending, left circumflex and right coronary artery were 37%, 26% and 29%, respectively (p = NS). In addition, restenosis was not influenced by the reference vessel size or morphologic features, such as eccentricity, calcification, plaque ulceration or the presence of a postangioplasty dissection. When an optimal angiographic result with a residual stenosis of <10% was achieved by initial stent placement, restenosis

Figure 2. Cumulative frequency plot of percent of lesions as a function of the minimal lumen diameter. The graphs show that stent implantation was associated with a significant gain compared with results for coronary angioplasty (PTCA); there was subsequent loss of initial gain at follow-up because of intimal hyperplasia.



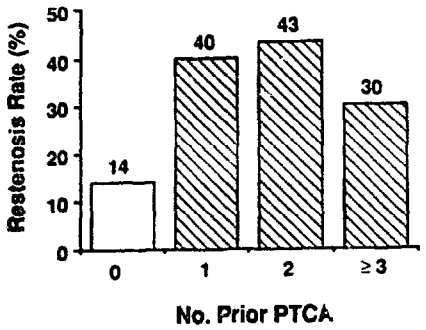


Figure 3. Restenosis after stent implantation. The restenosis rate is plotted for previously untreated lesions **(open bar)** and for lesions with one, two and three or more previous coronary angioplasty procedures **(hatched bars)**. The restenosis rate for previously untreated lesions was significantly less than that for lesions with previous angioplasty ($p < 0.001$). However, for lesions that were previously dilated, restenosis did not progressively increase as a function of the number of previous angioplasty procedures, suggesting a restenosis "plateau" for stents.

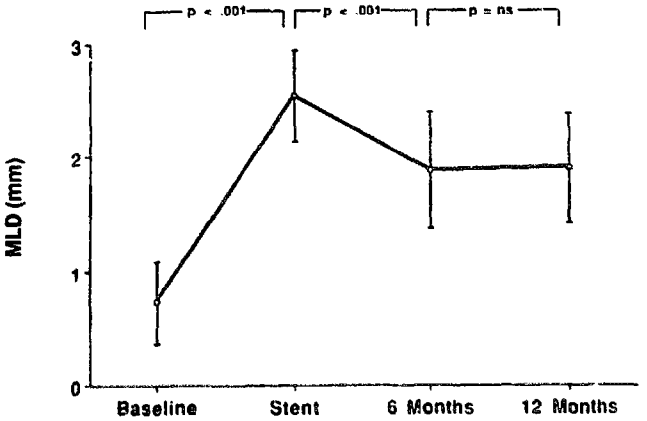


Figure 4. Temporal course of restenosis after intracoronary stent implantation. Quantitative coronary angiography was performed in 50 patients at baseline, immediately after stent placement, at 6 months after placement and again at 1 year. A significant loss in minimal lumen diameter (MLD) was noted during the 1st 6 months but not during the interval from 6 to 12 months, indicating that the presence of the endovascular prosthesis does not delay the usual time course of the restenosis process.

occurred in 27% of vessels versus 36% for lesions with a greater residual stenosis after stent placement ($p = 0.13$).

Late angiographic follow-up at 1 year. To assess whether the permanent metallic implant prolongs the time course over which intimal hyperplasia occurs, quantitative angiography was performed in a cohort of 50 patients who underwent a second follow-up catheterization at 1 year (Fig. 4 and 5). Lumen diameter was significantly smaller at 6 months than immediately after stenting (1.88 ± 0.51 mm vs. 2.54 ± 0.40 mm, $p = 0.0001$). In contrast, there was no further decline in minimal lumen diameter between 6 and 12 months (1.90 ± 0.48 mm at 12 months vs. 1.88 ± 0.51 mm at 6 months, p = NS). Similar findings were observed for percent diameter stenosis. Mean percent stenosis was 16 ± 13% at implantation, 34 ± 17% at 6 months and 34 ± 16% at 1 year. Angiographic restenosis (≥50% diameter stenosis) in this cohort was 18% (9 of 50) at 6 months versus 16% (8 of 50) at 1 year.

Clinical outcome. Clinical end points at 1-year follow-up are shown in Table 3. All adverse events, whether they occurred in the hospital or during late follow-up, were included in this analysis. The overall mortality rate was 0.7%. Myocardial infarction occurred in 11 patients (3.7%), including 7 (2.3%) with a Q wave infarction and 4 (1.3%) with a non-Q wave infarction. In 10 of these 11 patients, myocardial infarction was due to subacute stent thrombosis. In contrast, acute myocardial infarction after 1 year developed in only 1 (0.3%) of the 286 patients in whom early stent thrombosis did not occur.

For the entire study group, 80% of patients remained free after 1 year from any adverse clinical event (death, myocardial infarction or additional revascularization). Of the subgroup with previously untreated lesions, 87% were event-free; of the patients with prior angioplasty procedures, 77% were event-free.

In addition to the major adverse clinical end points just described, bleeding complications requiring either peripheral vascular surgery or blood transfusion occurred in 31 patients (10%). There were no instances of intracerebral hemorrhage in this study.

Discussion

This consecutive series of 300 patients with a 90% angiographic restudy rate demonstrates that implantation of single balloon-expandable Palmaz-Schatz stents is associated with excellent event-free survival after 1 year and a low angiographic restenosis rate in previously untreated lesions.

Comparison with previous studies. Previous reports of a self-expanding stent have shown excellent acute angiographic results with substantial improvement in lumen diameter immediately after stent implantation. Serruys et al. (1) reported an increase of lumen diameter from 1.21 mm at baseline to 1.88 mm after coronary angioplasty to 2.48 mm after stent placement. However, despite the improved angiographic appearance of the vessel after stent implantation compared with the result after angioplasty, a significant clinical benefit was not seen. Thrombosis occurred within 2 weeks in 25 (24%) of 105 patients and the 1-year mortality rate was an unacceptable 7.6%. Restenosis, defined as ≥50% narrowing at 6-month follow-up angiography, occurred in 14%.

The results of our study show that the long-term clinical outcome associated with the balloon-expandable stent is in sharp contrast to this earlier report. Despite similar quantitative angiographic results measured at the time of stent implantation, the rates of thrombosis and death were markedly lower in the current series. Our quantitative angiographic results show a very similar final stent minimal lumen diameter of 2.55 mm. However, thrombotic occlusion of the stent occurred in <5% and the 1-year mortality rate was <1%. Thus, despite

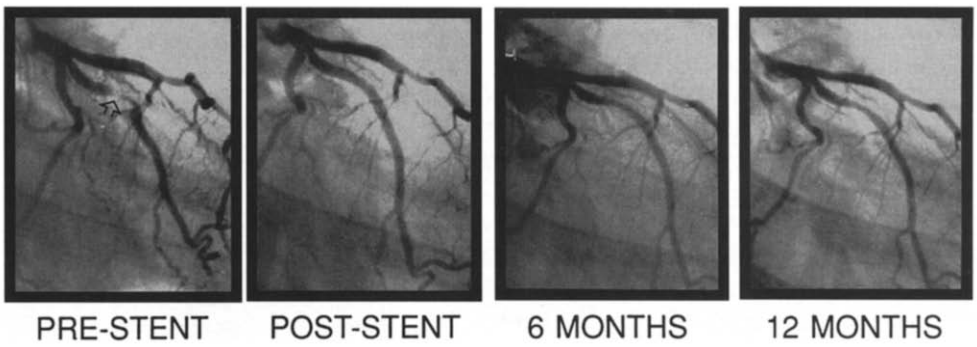


Figure 5. Serial coronary angiograms from a 48-year old man with unstable angina. Baseline (PRE-STENT) left coronary angiography demonstrates a high grade stenosis of the ramus medianus branch (arrow), which is reduced to a minimal lumen irregularity by stent placement (POST-STENT). At 6 months, evidence of neointimal ingrowth is apparent with a slight reduction in lumen diameter. Between 6 and 12 months, no further change in the lesion is observed.

a similar excellent immediate angiographic result, the reduced incidence of thrombosis noted in our series improved clinical outcome. Restenosis rates in our patients with previously untreated lesions (14%) were similar to those of the patients in the prior study (14%). The differences in thrombotic stent occlusion may be related to several factors including differences in device design, anticoagulation regimens and baseline patient characteristics.

A single-center study (3), using the Palmaz-Schatz stent in both the native arteries and venous bypass grafts, has reported an even lower thrombosis rate of 0.4%. However, the varying biologic behavior of bypass grafts compared with native vessels with respect to thrombosis may account in part for these optimistic results (10).

The time course of abrupt closure associated with stenting is different from that observed with conventional balloon angioplasty. Although there were no immediate in-laboratory vessel closures in our 300 patients, delayed thrombotic occlusion occurred in slightly less than 5% of the Palmaz-Schatz stents. This complication accounted for nearly all acute ischemic complications and, therefore, represents the most serious limitation of this therapy. Acute myocardial infarction developed in 10 of 14 patients with stent thrombosis but in only 1 of 286 patients without thrombosis. Accordingly, efforts to lessen this complication by improved techniques of stent deployment and by antithrombotic coatings are under development.

Mechanism of benefit conferred by stents. The restenosis rate of 14% noted in the group with previously untreated lesions is in sharp contrast to the restenosis rates of 30% to 40% reported after conventional balloon angioplasty (11–17). The mechanism by which stents reduce restenosis can be attributed to the enhanced immediate gain that is achieved compared with that after balloon angioplasty rather than to a reduction of late loss due to intimal hyperplasia (3,18). Thus, stenting of previously untreated lesions results in a wider initial lumen that can accommodate a relatively larger degree of neointimal ingrowth without producing a severe diameter stenosis. In contrast, higher rates of angiographic stenosis are observed for stents placed into restenotic lesions previously treated by balloon angioplasty. In addition, earlier reports of the Palmaz-Schatz stent (3,18) have shown a marked increase in restenosis rates when multiple stents are placed. For this reason, we chose to study patients who had implantation of a single stent.

Late clinical outcome of patients after coronary stent implantation. The clinical outcomes noted in our study compare favorably with those reported in prior studies of standard balloon angioplasty. In the National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry of 1985 to 1986 (9), major adverse events in 1,801 patients after 1 year of follow-up included death in 3.2%, myocardial infarction in 7.2%, coronary bypass grafting in 13.2% and repeat coronary angioplasty in 18.5%. Thirty-four percent of patients experienced one or more of these adverse events within 1 year. In the present stent series, the cumulative frequency of any adverse clinical event at 1 year was 20% for the entire study group and only 13% in the group with previously untreated lesions. These comparisons should be

Table 3. Clinical Follow-Up at 1 Year

Patient Group	No.	Death	MI	CABG	Repeat Angioplasty	No Event
All patients	300	1 (0.7%)	11 (3.7%)	24 (8.0%)	39 (13.0%)	240 (80%)
No prior angioplasty	83	1 (1.2%)	4 (4.8%)	7 (8.4%)	6 (7.2%)	72 (87%)
Prior angioplasty	217	1 (0.5%)	7 (3.2%)	17 (7.8%)	33 (15.2%)	168 (77%)
Stent thrombosis	14	1 (7.1%)	10 (71.4%)	7 (50.0%)	9 (64.3%)	1 (7%)
No thrombosis	286	1 (0.3%)	1 (0.3%)	17 (5.9%)	30 (10.5%)	239 (84%)

Values are expressed as number (%) of patients. CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

made with caution because of differences in patient groups and the evolution of standard angioplasty techniques since the National Heart, Lung, and Blood Institute report.

Limitations of the present study. This study has several important limitations. First, there was no concurrent control group of patients undergoing standard angioplasty for definitive comparisons to be made regarding stent implantation. Second, the number of patients reported in the group with previously untreated lesions was relatively small so that generalizations regarding restenosis rates in patients undergoing first-time revascularization are not yet warranted. Third, there were no data presented on the cost/benefit ratio for a procedure that prolongs hospital stay and incurs a substantial increase in short-term charges (19).

Clinical implications. Our data show that elective implantation of single Palmaz-Schatz stents in large native coronary arteries is associated with excellent long-term patency. In addition, this permanent intravascular implant does not prolong the temporal course of the restenotic process as demonstrated by follow-up angiography at 1 year. Most important, intracoronary stents conferred an excellent long-term clinical outcome. The incidence of death, myocardial infarction and the need for further revascularization procedures appears low when compared with findings in previous reports of standard balloon angioplasty or self-expanding stents. However, the potential for early coronary thrombosis and a relatively high rate of peripheral vascular complications remain major limitations of stenting. The findings of this multicenter study provided the framework leading to the Stent Restenosis Study (STRESS), a randomized trial comparing elective stent placement to balloon angioplasty in the treatment of previously untreated lesions in native coronary arteries.

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